UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA

ROY LASSITER, JENNIFER PURIFOY,	)	
Plaintiffs,	)	CASE NO.: 2:07-CV-00583
v.	)	
PACIFICARE LIFE & HEALTH INSURANCE COMPANY, UNITED HEALTHCARE SERVICES, INC., as successor in interest to Pacificare Life & Health Company**; ROBERT D. BELL** and Fictitious Defendants "A" through "R"	)	
Defendants.	)	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO REMAND

COME NOW the Plaintiffs, by and through their undersigned counsel of record, and provide the following Memorandum of Law in Support of Motion to Remand filed contemporaneously herewith.

INTRODUCTION

Plaintiffs filed this case against Pacificare Life and Health Insurance Company, United Healthcare Services, Inc., and Robert D. Bell in the Circuit Court of Bullock County, Alabama on May 23, 2007 (hereinafter collectively referred to as "Defendants" or "Pacificare"). Plaintiffs' Complaint brings state law claims asserting that Defendants fraudulently misrepresented material information, as well as engaged in other wrongful conduct that led to enrollment in the healthcare plan at issue, Pacificare's Secure Horizons program, which caused the Plaintiffs' damages.

This case is before this Court as a result of the Defendants' removal pursuant to 28 U.S.C. § 1441(b). At its core, Defendants rely on the erroneous argument that Plaintiffs' state law claims

are completely preempted by federal law, that is, the Medicare Act, as amended in 2003 by the Medicare Modernization Act ("MMA"). The Defendants' argument is wrong, and this case should be remanded, as this court lacks federal question jurisdiction over the Plaintiffs' state law claims.

I. Background on Medicare Advantage Plans

From a preliminary standpoint, it may be helpful to understand Medicare and its modifications over the years that led to the Plaintiffs' enrollment in the healthcare plan at issue. The Plaintiffs are Medicare beneficiaries who were fraudulently enrolled in a Medicare Advantage plan – the "Secure Horizons" plan offered by Pacificare (now known as United Healthcare). The term, "Medicare Advantage" plan, refers to a private healthcare plan offered to Medicare beneficiaries only. Medicare Advantage plans are federal statutory creations, which will be explained in detail below.

Enacted in 1965, Medicare is a federally run health insurance program benefitting primarily those who are 65 years of age and older. Before the recent extension of Medicare to cover a portion of prescription drug costs, Medicare covered only inpatient care through Part A and outpatient care through Part B. Parts A and B are fee-for-service insurance programs operated by the federal government. 42 U.S.C. § 1395c *et seq.* (Part A); 42 U.S.C. § 1395j *et seq.* (Part B).

In 1997 Congress enacted Medicare Part C to allow Medicare beneficiaries to opt out of traditional fee-for-service coverage under Parts A and B. 42 U.S.C. § 1395w-21 *et seq.* (Part C). Under Part C, beneficiaries can, among other things, enroll in "Medicare Advantage" plans, which are privately-run managed care plans that provide coverage for both inpatient and outpatient

services. *Id.* § 1395w-22(a)(1).[1] Basically, under Medicare Advantage plans, eligible individuals (members) can elect to receive Medicare benefits through a Medicare Advantage plan of health insurance offered by a private health maintenance organization (HMO). In addition to receiving funding from Medicare for each enrollee, an HMO charges its enrollees a combination of monthly premiums or co-pays for various benefit plans. A Medicare beneficiary typically enrolls in a Medicare Advantage plan because the HMO administering the particular plan claims to provide greater benefits than those provided under traditional Medicare.

Critically, when a beneficiary enrolls in a Medicare Advantage plan, his or her healthcare is tendered from Medicare to the HMO. Medicare no longer provides or pays for healthcare. The enrollee must then use that HMO's network of doctors and healthcare providers to receive healthcare coverage. If the enrollee fails to seek medical treatment from the plan's network of doctors and providers, they may incur the costs of that treatment.

Prior to 2003 Medicare coverage did not include prescription drugs. In 2003 Congress enacted the Medicare Modernization Act ("MMA") to extend partial coverage for prescription drugs to Medicare beneficiaries under Medicare Part D. *See* Pub.L. No. 173, Tit. I (2003) (Part D). Under the MMA, participation in Medicare Part D is voluntary for non-dual-eligible beneficiaries (i.e., persons who were not indigent and were not receiving state Medicaid benefits and services). 42 U.S.C. § 1395-101(a). Medicare Advantage plans may offer Part D coverage to their enrollees. *Id.* § 1395-101(a)(1)(b)(I). Thus, Medicare Advantage plan enrollees may receive all of their Medicare coverage through a single managed care plan. If a Medicare beneficiary is not enrolled

[1]Medicare Advantage Plans were once called "M+C" or "Medicare + Choice" plans upon their creation in 1997.

in a Medicare Advantage plan, he or she may still enroll in a stand-alone Part D prescription drug plan. Part D prescription drug coverage took effect in January of 2006.

The Center for Medicare and Medicaid Services (CMS), formerly known as HCFA, is an administrative subdivision of the United States Department of Health and Human Services that directly administers and oversees the entire Medicare program, including Medicare Advantage plans and Part D plans. In order to operate a Medicare Advantage plan, an HMO must have a contract with the CMS. The CMS sets forth guidelines that an HMO and its agents must follow when marketing a Medicare Advantage plan. Likewise, the CMS sets forth guidelines for Part D prescription drug providers to follow when administering their prescription drug plans. These guidelines will be discussed in more detail, *infra*.

II. The Plaintiffs' claims

The original Complaint shows that the Plaintiffs were Medicare beneficiaries who were enrolled in Pacificare's Secure Horizons plan, which is a "Medicare Advantage" plan as described above. Because the Secure Horizons plan also contained a Part D (prescription drug) benefit, the Plaintiffs were to receive all of their Medicare coverage through a single managed care plan. The problem, however, was that by enrolling in Pacificare's Secure Horizons plan, the Plaintiffs could only go to doctors who were a part of the Pacificare network. (See Complaint, ¶¶10-18, attached as Exhibit A to Defendants' Notice of Removal). In other words, the Plaintiffs gave up their right to go to doctors or healthcare providers who were not in the network, which included the Plaintiffs' regular doctors.

The crux of the Plaintiffs' lawsuit is that the Defendants misrepresented the true nature of the Secure Horizons plan by leading the Plaintiffs to believe that they could still use original

Medicare and go to their regular doctors and healthcare providers. (See Complaint). The Plaintiffs did not know they were enrolling in a limited network. *Id.* By enrolling in the Secure Horizons plan, the Plaintiffs no longer had their original Medicare coverage. *Id.* The practical effect was that the Plaintiffs' original "red, white and blue" Medicare card no longer worked. *Id.* When the Plaintiffs went to their regular doctors and healthcare providers, *who were not a part of the Pacificare network*, they had no means of paying for the services. *Id.* They no longer had Medicare coverage, and they incurred bills as a result. *Id.*

III. The Defendants' arguments for removal

As stated previously, the Defendants' argument for removal rests on the sole contention that this Court has federal question jurisdiction over the Plaintiffs' claims. The Defendants specifically assert that the Plaintiffs' claims for relief arise under the Medicare Act, 42 U.S.C. §1395w-21 to w-28, as amended by the Medicare Modernization Act (MMA) of 2003. (See Notice of Removal, ¶3). The Defendants argue that the Plaintiffs' claims are totally preempted by §1395w-26(b)(3) based on three (3) specific grounds:

> (1) that the Plaintiffs' claims of fraud directly implicates standards set forth for enrollment, including Pacificare's marketing efforts and materials under §1395w-101(b)(1)(A) and 42 C.F.R. §423.50 (2005);
>
> (2) that the Plaintiffs, "in effect complain of benefit or coverage determinations governed by the Medicare Act/MMA"; and
>
> (3) the Plaintiffs' claim of reduced benefits and denial of medical care "implicates the grievance and appeals process established under the Medicare Act/MMA." 42 C.F.R. §§423.560, 423.566, 423.568, 423.570, 423.580-90, 423.600-04, 423.610, 423.630 (2005).

(See Notice of Removal, ¶4). For the reasons set forth below, however, the Defendants' preemption argument is not supported by law.

ARGUMENT

I. Plaintiffs' claims have not invoked federal question, in light of the well-pleaded complaint rule.

Whether a claim arises under federal law so as to confer federal question jurisdiction under 28 U.S.C. § 1331 is governed by the "well-pleaded complaint" rule, which provides that "federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). Because the "well-pleaded complaint" rule provides for the determination of jurisdiction solely on the basis of the plaintiff's complaint, the rule makes the plaintiff master of the claim, and federal jurisdiction may be avoided by exclusive reliance on state law. *See Caterpillar*, 482 U.S. at 392.

One need look no further than the Plaintiffs' Complaint to see that the Plaintiffs bring only state law claims in their Complaint. The Complaint specifically states:

> Plaintiffs make no claims pursuant to federal law and further make no claims that would give rise to any federal cause of action. Plaintiffs' claims are based solely upon applicable state law.

(See Complaint, ¶18, Exhibit A to Defendants' Notice of Removal). Accordingly, based on the complaint alone, federal question jurisdiction is lacking.

The Plaintiffs acknowledge the one exception to the well-pleaded complaint rule – the "complete pre-emption" doctrine, which provides that "once an area of state law has been completely pre-empted, any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law." *Caterpillar*, 482 U.S. at 393. The Defendants argue that the Plaintiffs' claims are completely preempted by §1395w-26(b)(3) of the MMA, which states:

> The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

As will be explained below, the argument is unsupported by federal law.

II. Plaintiffs' claims are not completely preempted by §1395w-26(b)(3) of the MMA.

The Supreme Court has found "complete pre-emption" of state-law claims in only a very few instances, for example, § 301 of the Labor Management Relations Act of 1947, 29 U.S.C.A. § 185, commonly referred to as the LMRA, *Avco Corp. v. Aero Lodge No. 735,* 390 U.S. 557, 88 S.Ct. 1235 (1968); and § 502 of the Employee Retirement Income Security Act of 1974, 29 U.S.C.A. § 1132, commonly referred to as ERISA, *Metropolitan Life Ins. Co. v. Taylor,* 481 U.S. 58, 107 S.Ct. 1542 (1987). The courts have identified three factors as critical to a finding of complete pre-emption. First, because "the touchstone of the federal district court's removal jurisdiction is ... the intent of Congress," *Taylor,* 481 U.S. at 66, 107 S.Ct. at 1548, the courts have concluded that there should be evidence of a congressional intent to make the state claim falling within the scope of the relevant federal statute removable to federal court.

Secondly, the federal law must also "displace" the state law claim with a cause of action. In *Taylor,* complete preemption was found because the "state common law claims are not only pre-empted by ERISA but also displaced by ERISA's civil enforcement provision." 481 U.S. at 60, 107 S.Ct. at 1544. *See also Allstate Ins. Co. v. 65 Sec. Plan,* 879 F.2d at 93 ("The doctrine of complete preemption applies only ... when the enforcement provisions of a federal statute create a federal cause of action vindicating the same interest that the plaintiff's cause of action seeks to vindicate"); *Willy v. Coastal Corp.,* 855 F.2d 1160, 1165 (5th Cir. 1988) ("a federal action cannot be found to

so completely displace state claims ... unless there would have been a federal cause of action under the preempting federal law"), *aff'd on other grounds,* 503 U.S. 131, 112 S.Ct. 1076 (1992).

Third, the jurisdictional and enforcement provisions in the LMRA or ERISA must have a close parallel in the federal claims at issue. In *Taylor,* the Supreme Court noted that, even with ERISA's extensive civil enforcement provisions, it "would be reluctant to find that extraordinary pre-emptive power," 481 U.S. at 65, 107 S.Ct. at 1547, but for the fact that ERISA's civil enforcement provision paralleled those in the LMRA, a statute where the Court had previously found such power. *Id.*

The defendant has the burden of demonstrating that a substantial question of federal law is necessary to the resolution of the Plaintiffs' claims stated in their Complaint. See *Franchise Tax Board v. Const. Laborers Vacation Trust*, 463 U.S. 1 (1983); *see also Kidd v. Southwest Airlines*, 891 F.2d 540, 542-43 (5th Cir.1990); *First Nat. Reserve, L.C. v. Vaughn,* 931 F.Supp. 463, 468 (E.D.Tex.1996); *Rogers v. Modern Woodmen of America* ,1997 WL 206757, *4 (N.D. Miss.,1997).

A. There is evidence that Congress did <u>not</u> intend for preemption of the Plaintiffs' state law claims.

Here, there is no evidence of a congressional intent to make the Plaintiffs' state claims, which purport to fall within the scope of §1395w-26(b)(3) of the MMA statute, removable to federal court. In fact, there is direct evidence to the contrary. The Rules and Regulations section of a publication of the <u>Federal Register</u>, which gives policy statements and interpretations of federal statutory rules, specifically addressed the extent of preemption in the field of Medicare Advantage plans and §1395w-26(b)(3) of the MMA. While this specific section pertains to Part D prescription

drug plans, the publication concludes that the same preemption laws apply to Medicare Advantage plans. It states:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, **tort law**, labor law, civil rights law, and similar areas of law would, we believe, continue in effect and PDP sponsors in such states would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where the Congress intended us to regulate – such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors.

70 Fed.Reg., No. 18, p. 4319 (January 28, 2005) (emphasis added) (attached hereto as Exhibit A). The Register echoes the same conclusion in a latter comment:

> *Comment*: One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language of section 1856(b)(3) of the Act. This insurer requested that CMS consider making clear that *all* State laws and regulations . . . are preempted with respect to MA and Part D plans.
>
> *Response*: As noted in the proposed rule, *we do not believe that either the principles of Federalism or the statute justify a broad preemption interpretation*. *Id.* at 4320 (emphasis added).

Based on the above statements, it is clear that preemption was not meant to cover state tort claims in connection with sales and marketing practices of Medicare Advantage plans. Indeed, the Comment went to great lengths to point out the areas that it believes Congress intended Medicare to regulate: (1) the rules governing pharmacy access, (2) formulary requirements for prescription drug plans, and (3) marketing standards governing the information disseminated to beneficiaries by PDP sponsors. 70 Fed.Reg. 4319. First, the Plaintiff is not a State and, thus, is not attempting to impose State guidelines on the three areas mentioned above, much less impose more restrictive guidelines or rules that directly conflict. Secondly, none of the Plaintiffs' claims in the instant

lawsuit pertain in any way to the rules governing pharmacy access, formulary requirements, or marketing guidelines for information disseminated to beneficiaries by PDP (prescription drug provider) sponsors. Although the Plaintiffs' claims are based on improper sales conduct by the agent, i.e., fraud and negligence, the Plaintiffs' state law claims are not attempting to impose additional or stricter marketing standards or guidelines for information disseminated by a Part D provider. Indeed, the Plaintiffs' state law claims do not impose or trigger any State standards in the area regulated whatsoever.

In addition to congressional intent, evidence of the CMS's intent with respect to preemption is instructive. Two bulletins issued by the Alabama Commissioner of Insurance, Walter Bell, addressed the inappropriate marketing activities of Medicare Advantage producers in Alabama. In a bulletin dated February 16, 2006, Commissioner Bell stated:

> [S]tate law and regulatory provisions regarding producer activity apply to the marketing of Medicare Part D . . . . CMS will refer complaints it receives about producers licensed in this state to the Alabama Department of Insurance. This bulletin reminds licensed producers that they are subject to all laws and regulations of this state, including those relating to the duty of good faith and fair dealing, the suitability of sale, and the prohibitions against misrepresentation, churning, and high pressure sales tactics . . . . **Any proven misconduct will be prosecuted under the laws of this state**. (AL Insurance Bulletin 2-16-2006, Medicare Part D Marketing, attached hereto as Exhibit B) (emphasis added).

Again, while this bulletin specifically addressed the marketing of Medicare Part D, it relates to the cross-selling of Medicare Advantage plans. Thus, sales and marketing conduct related to Medicare Advantage plans is directly implicated in this bulletin.

Moreover, the Alabama Department of Insurance issued another bulletin on June 8, 2007, which specifically addressed the marketing of Medicare Advantage plans. The bulletin set forth

conditions for the marketing of these plans. In addition, the bulletin stated, "The four conditions set forth above are in addition to any other requirements set out in Alabama Department Regulation, Chapter 482-1-071." (AL Insurance Bulletin 6-8-2007, Medicare Advantage Insurance Producers, attached as Exhibit C). Notably, chapter 482-1-071 of the Alabama Administrative Code sets forth state standards for marketing of these products.

Therefore, in light of the recent actions and comments of federal and state agencies, *viz.* the CMS and the Alabama Insurance Commissioner, it is clear that the intent of the preemption section of the statute was not to cover marketing activity of Medicare Advantage products, much less state causes of action arising from improper sales and marketing conduct. This matter should, therefore, be remanded to state court on this basis alone. Furthermore, even if there was evidence of congressional intent for complete preemption here, there is no evidence that the Medicare Act and the 2003 MMA displaces the Plaintiffs' state law claims with an equal cause of action of its own.

B. The Medicare Act/MMA does not displace the Plaintiffs' claims with a cause of action.

As set forth above, Supreme Court has warned that the doctrine of complete preemption applies only when the enforcement provisions of a federal statute create a federal cause of action vindicating the same interest that the plaintiff's cause of action seeks to vindicate. *See Taylor,* 481 U.S. at 60. In the present action, neither the Medicare Act nor its 2003 amendment create a federal cause of action that displaces the Plaintiff's state law claims. The Defendants cite numerous provisions of the Medicare Act and the MMA and argue that the Plaintiffs' claims are "in effect" complaints for benefits and coverage determinations that implicate the grievance and appeals process established under the Medicare Act/MMA. (See Notice of Removal, ¶4, citing 42 C.F.R.

§§423.560, 423.566, 423.568, 423.570, 423.580-90, 423.600-04, 423.610, 423.630 (2005). None of these provisions, however, provides a private right of action or remedy for an enrollee, much less displaces a cause of action with a federal cause of action vindicating the same interests.

There is not a single request in the Plaintiffs' complaint seeking a coverage determination or an appeal of an unpaid claim, despite the Defendants' attempts to couch the Plaintiffs' Complaint as such. The Plaintiffs are not claiming that Pacificare wrongfully denied a claim. Nor are they claiming that Medicare wrongfully denied a claim. The Plaintiffs have no grievance with Medicare. Their only dispute is with Pacificare and its agent who fraudulently misrepresented the product. However, neither the Medicare Act nor its 2003 amendment provide a remedy that the Plaintiffs' complaint seeks to redress. Because the Plaintiffs are not claiming that Pacificare should have paid a claim, there is no unpaid claim from which the Plaintiffs can appeal.

The Federal Register, again, provides guidance on this point. Commenting on preemption and the grievance procedures offered under the Medicare Act/MMA, it has been noted:

> In addition, we did not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between plans and their subcontractors. We believe that the Congress did not intend for our regulations to supersede each other and every State requirement applying to plans – particularly those for which the Secretary lacks expertise and authority to regulate. Thus, we did not believe, for example, that wrongful death or similar lawsuits based upon tort law would be superseded by the appeals process established in these regulations. . . . Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee will still have State remedies available in cases in which the legal issue before the court is independent of an issue related to an organization's status as a stand alone PDP or MA-PD plan.

70 Fed.Reg., No. 18, 4362 (January 28, 2005) (attached hereto as Exhibit D). It is therefore clear that Congress did not intend for any grievance procedure offered under the Medicare Act to serve as a substitute for any private right of action such as those asserted in the Plaintiffs' Complaint.

Furthermore, even if the Plaintiffs' Complaint, which is based on fraudulent sales and marketing conduct, "implicates standards set forth for enrollment, including Pacificare's marketing efforts and materials under §1395w-101(b)(1)(A) and 42 C.F.R. §423.50 (2005)", as claimed by the Defendants, these marketing standards do not offer a private right of action that displaces the state law claims in the Complaint. These standards simply set forth rules and guidelines that an HMO like Pacificare and its agents must follow when marketing the Medicare Advantage product. The rules prohibit, for example, a marketer from misrepresenting the product or making unsolicited visits to prospective enrolles. Such marketing rules and guidelines only provide the CMS with the opportunity to fine an agent or entity that is found to be in violation. The rules do not grant a private right of action to an enrollee who is the victim of such a violation. Thus, if an agent misrepresents the product and violates every rule or guideline set forth by the CMS, the offender only stands to be fined by the CMS. The guidelines certainly do not grant an enrollee a private cause of action to sue. Nor do the grievance procedures touted by the Defendants provide any such remedy either. In sum, neither the Medicare Act nor its 2003 amendment (MMA) provide a private right of action or remedy for an enrollee, much less displace a cause of action with a federal cause of action vindicating the same interests. Accordingly, this case should be remanded to state court, as the critical second prong of the preemption analysis cannot be met.

C. There is no jurisdiction or enforcement provision in the Medicare Act/MMA that parallels the LMRA or ERISA.

In addition to evidence of congressional intent and displacement, the third requirement for preemption is that the jurisdictional and enforcement provisions in the LMRA or ERISA must have a close parallel in the federal claims at issue. In *Taylor,* the Supreme Court noted that, even with ERISA's extensive civil enforcement provisions, it "would be reluctant to find that extraordinary pre-emptive power," 481 U.S. at 65, 107 S.Ct. at 1547, but for the fact that ERISA's civil enforcement provision paralleled those in the LMRA, a statute where the Court had previously found such power. *Id.*

There is not a single jurisdictional and civil enforcement provision in the Medicare Act/MMA that even arguably parallels those of the LMRA or ERISA. Simply put, the Medicare Act/MMA is not ERISA or the LMRA and has not such power. Accordingly, the Defendants' claim for complete preemption fails.[2]

III. Pacificare has failed to show that a substantial question of federal law is necessary to the resolution of the claims asserted by the Plaintiffs.

Even if Plaintiffs' claims involve construction of federal law, Defendants' argument that Plaintiffs' claims are pre-empted because they "relate to standards established under the Medicare Act/MMA" is not sufficient to confer removal jurisdiction. The fact that a state law claim relates

---

[2]For a similar legal analysis based upon the Medicare Act's preemption provision *prior to* the 2003 amendment, see *Burke v. Humana Ins. Co*, 1995 WL 841678 (M.D. Ala.), which the Court rejected the defendant's attempt to remove a similar case on the basis that the plaintiffs' claim were preempted by the Medicare Act. *See also Grace v. Interstate Life & Accident, Ins. Co.*, 916 F.Supp. 1185 (M.D. Ala. 1996), which the Court concluded that the Medicare Act did not provide complete preemption and, thus, remanded the case.

to a federal issue, or involves an interpretation of a federal law, does not necessarily establish a federal question and provide removal jurisdiction. *See Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986). Accordingly, Defendants have failed to meet their burden; thus, removal of this action was improper, and remand is appropriate.

CONCLUSION

Defendants have failed to meet their burden of demonstrating that a substantial question of federal law is necessary to resolve Plaintiffs' claims. Moreover, Pacificare's argument that Plaintiffs' claims are "completely pre-empted" by federal law is without merit. Accordingly, this case is due to be remanded to its proper forum in the Circuit Court of Bullock County, Alabama.

Respectfully submitted,

/s/ J. Matthew Stephens
Robert G. Methvin, Jr. (MET009)
J. Matthew Stephens (STE153)
Rodney E. Miller (MIL126)

OF COUNSEL:
MCCALLUM, METHVIN & TERRELL, P.C.
2201 Arlington Avenue South
Birmingham, AL 35205
Telephone: (205) 939- 0199
Facsimile: (205) 939-0399

/s/ L. Cooper Rutland
L. Cooper Rutland, Jr. (RUT010)

OF COUNSEL:

RUTLAND & BRASWELL, L.L.C.

208 N. Prairie Street

P.O. Box 551

Union Springs, AL 36089

CERTIFICATE OF SERVICE

I hereby certify that on 17TH day of July, 2007, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following CM/ECF participants:

Philip H. Butler

George B. Harris

William C. McGowin

BRADLEY, ARANT, ROSE & WHITE, LLP

401 Adams Avenue, Suite 780

Montgomery, AL 36104

Telephone: (334) 956-7700

Paula Denney

John K. Edwards

JACKSON, WALKER, LLP

1401 McKinney, Suite 1900

Houston, TX 77010

/s/ J. Matthew Stephens

COUNSEL

CERTIFICATE OF SERVICE

I hereby certify that on 17TH day of July, 2007, I placed a copy of the foregoing document in the U.S. mail to the following party:

Robert D. Bell
Route 1, Box 995
Shellman, GA 39886

/s/ J. Matthew Stephens
COUNSEL

Exhibit

A

required to comply with the solvency standards established by us. In the event the State ultimately denied the application, we stated that we could extend the waiver through the contract year as we deemed appropriate to provide for transition.

In the final rule we have clarified, with the addition the distinctions between the temporary waiver (for regional plans) and the waiver for entities seeking to offer a plan in a single State, the timeline for processing the application for the waiver and the length of the waiver itself. Thus in new § 423.415(c) we clarify that Secretary will determine the time period appropriate for the processing of the application and in new § 423.415(d), we repeat the policy of the proposed rule that in no case will the temporary waiver extend beyond the end of the calendar year.

4. Solvency Standards for Non-Licensed Entities (§ 423.420)

In proposed § 423.420, we specified that sponsors that have been granted a waiver by us must maintain reasonable financial solvency and capital adequacy.

Solvency standards have been developed after statutorily required consultation with the National Association of Insurance Commissioners. These standards are undergoing internal CMS review. We anticipate that these standards, which are required to be published by January 1, 2005 will be published on the CMS website in the near future in conjunction with the initial application forms for PDP organizations. These solvency standards will include such items as required minimum net worth and liquidity requirements as well as reporting requirements for future PDPs who have received waiver of State licensure. We are adopting the policy we proposed for reasonable financial solvency and capital adequacy in this final rule.

5. Preemption of State Laws and Prohibition of Premium Taxes (§ 423.440)

In the August 4, 2004 proposed rule, we stated that we would implement section 1860D–12(g) of the Act at proposed § 423.440(a), by specifying that to the extent there are Federal standards, those standards supersede any State Law.

We proposed that for purposes of Part D, with the exceptions of State licensing laws or State laws related to plan solvency, State laws would not apply to prescription drug plans and PDP sponsors.

The proposed rule for the Medicare Advantage program also discussed preemption of State laws, and because Part D and Part C incorporate the same preemption laws at section 1856(b)(3) of the Act, we believe it is necessary to summarize those discussions in this final rule.

In the Medicare Advantage proposed rule, we noted that prior to enactment of the MMA, section 1856(b)(3) of the Act provided for two types of preemption: general and specific. The presumption was that a State law was not preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories where preemption was presumed. (These four categories were: benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans.)

We concluded that the MMA reversed this presumption and provided that State laws are presumed to be preempted unless they relate to licensure or solvency. We also referenced the Congress' intent that the MA program, as a Federal program, operate under Federal rules, and referred to the Conference Report of the MMA as making clear the Congress' intent to broaden the scope of preemption through its change to section 1856(b)(3) of the Act. See 69 FR 46866, 46904. We believe that because the Congress incorporated the same preemption standard into the Part D program, and because the Congress required the preemption rules to apply consistently in Parts C and D, this same reasoning would apply to Part D.

In addition, in the proposed rule for Part D, we stated that although the Congress included broad preemption rules in section 1856(b)(3) of the Act, we did not believe that the Congress intended for each and every State requirement applying to PDP sponsors to become null and void. Specifically, we stated:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where the Congress intended us to regulate—such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly. (69 FR 46696.)

We also recognized that while the Congress specifically stated that State licensure and solvency laws would not be preempted, this did not mean that States could condition licensure on a sponsor meeting requirements unrelated to what we would consider licensure requirements. We also addressed this issue in the Medicare Advantage proposed rule, explaining:

> We believe that the exception for State laws that relate to "State licensing" must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that-absent Federal preemption-must be met as a condition for keeping a State license. If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. ... Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans. (69 FR 46904.)

We are adopting these preemption interpretations as our final policy. We also note that in the accompanying regulation text we have replaced PDP sponsor with Part D sponsor, as we believe that the preemption of State law and the prohibition against imposition of premium taxes should operate uniformly for all Part D sponsors. We note that licensure requirements in this Part continue to apply only to PDP sponsors, as other Part D sponsors (such as MA organizations and cost-based HMOs and CMPs) are subject to their own licensing laws.

Comment: One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language of section 1856(b)(3) of the Act. This insurer requested that CMS consider making clear that all State laws and regulations (with the exception of State licensing and solvency laws) are preempted with respect to MA and Part D plans.

Response: As noted in the proposed rule, we do not believe that either the

principles of Federalism or the statute justify such a broad preemption interpretation. We do not believe, for example, we could preempt all State environmental or civil rights laws, nor do we believe it was the Congress' intent to do so. The preemption in section 1860D–12(g) of the Act is a preemption that operates only when CMS actually creates standards in the area regulated. To the extent we do not create any standards whatsoever in a particular area, we do not believe preemption would be warranted.

Comment: A pharmaceutical manufacturer and a pharmaceutical manufacturing association requested clarification from us that it is not our intent to preempt any State pharmacy laws dealing with the practice of therapeutic substitution.

Response: In general, we do not think we have the authority to preempt State pharmacy licensing laws dealing with the practice of therapeutic substitution and we do not intend to establish standards in this area. However, it should be noted that the forthcoming electronic prescription standards do have the potential to impact State pharmacy practices and such standards could preempt State pharmacy practice laws and regulations that conflict with them.

We are adopting the requirements of the proposed rule with the technical and clarifying changes noted throughout this preamble. We are also adopting the premium tax prohibition included in the proposed without modification. Both rules are found at § 423.440

J. Coordination Under Part D Plans with Other Prescription Drug Coverage

Proposed subpart J set forth the application of Medicare Part D rules to Medicare Part C plans; established waivers for employer-sponsored group prescription drug plans, MA-PD plans, cost plans, and PACE organizations; and established requirements for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage.

Below we summarize the proposed provisions of subpart J and respond to public comments. (Please refer to the August 2004 proposed rule (69 FR 46696) for a detailed discussion of our proposals.)

1. Overview and Terminology (§ 423.454)

Subpart J implemented sections 1860D–2(a)(4), 1860D–2(b)(4)(D), 1860D–11(j), 1860D–21(c), 1860D–22(b), 1860D–23(a), 1860D 3(b), 1860D–23(c), 1860D–24(a), 1860D–24(b), and 1860D–24(c) of the Act, as added to the Act by section 101(a) of the MMA. We proposed that, in general, the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA-PD plans, although certain waivers are available. In addition, we implemented section 1860D–22(b) of the Act at proposed § 423.458(c) providing us the authority to waive the requirements of this part for employer-sponsored group prescription drug plans.

a. Part D Plans

Unless otherwise indicated, references to "Part D plans" in the proposed rule referred to any or all of MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans. Likewise, the term "Part D plan sponsor" referred to MA organizations offering MA-PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. We have moved the definition of "Part D plan" to § 423.4 of our final rule and expanded the definition such that it includes cost plans and PACE organizations offering qualified prescription drug coverage. Similarly, we have revised the definition of "Part D sponsor" under § 423.4 of our final rule to include cost plans and PACE organizations offering qualified prescription drug coverage.

b. Employer-sponsored Group Prescription Drug Plan

We used the term "employer-sponsored group prescription drug plan" to mean a prescription drug plan under a contract between a PDP sponsor or MA organization offering an MA-PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations (or combination thereof) to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program (SPAP)

We defined an SPAP, for purposes of this part, as a program operated by or under contract with a State if it:

(1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(2) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(3) Meets the benefit coordination requirements specified in this part; and

(4) Does not change or affect the primary payer status of a Part D plan.

Comment: Although one commenter supported our proposed definition of the term "SPAP," several commenters urged us to allow SPAPs to endorse one or more Part D plans for SPAP enrollees. They believe that the non-discrimination criteria contained in the definition of the term SPAP should be designed to maximize the efficiency and effectiveness of offering benefits that supplement the benefits available under Part D coverage to enrollees. Some of these commenters believe that a preferred plan approach, if accomplished via a competitive bid process, supports the competitive, market-based model that the Congress envisioned. One commenter stated that such an approach would help it to "ratchet down" administrative costs. Another commenter asserted that the statute does not prohibit a State from providing consumer advice to its SPAP enrollees regarding which Part D plan might work best with an SPAP or offer the best value.

Commenters believe that this interpretation is consistent with the intent to establish an effective coordination mechanism between SPAPs and Part D plans. Defining non-discrimination in a way that prohibits SPAPs from designating preferred Part D plans and prohibiting auto-enrollment of SPAP beneficiaries into preferred plans would not facilitate enrollment in Part D plans and would further complicate, rather than promote, coordination between Part D plans and SPAPs.

Response: Section 1860D–23(b)(2) of the Act defines an SPAP, in part, as a program that "in determining eligibility and the amount of assistance to Part D enrollees, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled." We are interpreting the non-discrimination language in section 1860D–23(b)(2) of the Act and § 423.464(e)(1)(ii) of our final rule to mean that SPAPs, if they offer premium assistance or supplemental assistance for Part D cost sharing, must not only offer equal assistance to beneficiaries enrolled in all Part D plans available in the State, but also may not steer beneficiaries to one plan or another through benefit design or otherwise. We believe that the law intends that all Part D plans in a State be given comparable opportunities. Requiring States to coordinate with all Part D plans, without discrimination, levels the playing field for Part D plans that want to provide benefits in a particular State.

We further interpret section 1860D–23(b)(2) of the Act as prohibiting SPAPs from automatically enrolling ("auto-enrolling") beneficiaries into a preferred

Exhibit

B

BOB RILEY
GOVERNOR

STATE OF ALABAMA
DEPARTMENT OF INSURANCE
201 MONROE STREET, SUITE 1700
POST OFFICE BOX 303351
MONTGOMERY, ALABAMA 36130-3351
TELEPHONE: (334) 269-3550
FACSIMILE: (334) 241-4192
INTERNET: www.aldoi.gov

WALTER A. BELL
COMMISSIONER

ASSISTANT COMMISSIONER
RAGAN INGRAM

DEPUTY COMMISSIONER
D. DAVID PARSONS

CHIEF EXAMINER
RICHARD L. FORD

STATE FIRE MARSHAL
RICHARD MONTGOMERY

GENERAL COUNSEL
REYN NORMAN

RECEIVER
DENISE B. AZAR

LICENSING MANAGER
JIMMY W. GUNN

BULLETIN

TO: All Insurers Licensed in Alabama

FROM: Walter A. Bell, Commissioner of Insurance

DATE: February 16, 2006

RE: Medicare Part D Marketing

Since October 1, 2005, marketing activity for the new Medicare prescription drug benefit, Medicare Part D, has been permissible. According to the Centers for Medicare & Medicaid Services (CMS), only state-licensed insurance producers may engage in marketing activity. The Medicare Modernization Act does not preempt producer licensing laws. Thus, state law and regulatory provisions regarding producer activity apply to the marketing of Medicare Part D.

CMS has received complaints about alleged misconduct by licensed producers with regard to Medicare Part D marketing. CMS will refer complaints it receives about producers licensed in this state to the Alabama Department of Insurance. This bulletin reminds licensed producers that they are subject to all laws and regulations of this state, including those relating to the duty of good faith and fair dealing, the suitability of sale, and the prohibitions against misrepresentation, churning, and high pressure sales tactics.

We view with a high degree of skepticism the use of a lead relating to Part D marketing activity to cross-sell other insurance products of any type. The new Part D benefit is fundamentally confusing for the Medicare beneficiary. It would be unwise for the producer to take advantage of the Part D lead to sell other insurance products to a Medicare beneficiary for which he or she may not be suited.

Allegations of misconduct related to Part D marketing will be thoroughly investigated by this office. Any proven misconduct will be prosecuted under the laws of this state relating to producer licensing.

WAB/EB/bc

Exhibit

C

BOB RILEY
GOVERNOR

STATE OF ALABAMA
DEPARTMENT OF INSURANCE
201 MONROE STREET, SUITE 1700
POST OFFICE BOX 303351
MONTGOMERY, ALABAMA 36130-3351
TELEPHONE: (334) 269-3550
FACSIMILE: (334) 241-4192
INTERNET: www.aldoi.gov

WALTER A. BELL
COMMISSIONER

ASSISTANT COMMISSIONER
RAGAN INGRAM

DEPUTY COMMISSIONER
D. DAVID PARSONS

CHIEF EXAMINER
RICHARD L. FORD

STATE FIRE MARSHAL
EDWARD S. PAULK

GENERAL COUNSEL
REYN NORMAN

RECEIVER
DENISE B. AZAR

LICENSING MANAGER
JIMMY W. GUNN

BULLETIN

TO: All Medicare Advantage Companies

FROM: Walter A. Bell, Commissioner of Insurance

DATE: June 8, 2007

RE: Medicare Advantage Insurance Producers

It has come to the attention of the Department some Medicare Advantage insurance producers are marketing and soliciting Alabama senior citizens in a deceptive and inappropriate manner. In some cases the agent has provided a business card that was designed so as to give the appearance the agent represents Medicare.

Therefore, all insurance producers marketing Medicare Advantage in this state must do the following:

1. Each insurance producer must leave an identifying card with the insured.

2. This card must only represent that the producer is an insurance agent and may identify the insurance company said producer represents.

3. The insurance producer may not under any circumstances say, do, or leave any materials including a business card that would cause a prospective buyer to misunderstand the organization the producer represents.

4. No check for the Medicare Advantage product may be made out to any named entity other than the insurance company.

The four conditions set forth above are in addition to any other requirements set out in Alabama Department Regulation, Chapter 482-1-071.

WAB/EB/ss

Exhibit

D

8. Federal Preemption of Grievances and Appeals

Section 232(a) of the MMA amended section 1856(b)(3) of the Act so that it now reads: "The standards under this part shall supersede any State law or regulation (other than State licensing laws or State law relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." Section 1860D–12(g) of the Act then incorporates this preemption rule for plans.

We believe that the grievance procedures for the Part D Drug Program under Title I must be the same as those that apply to the MA program under Title II. In the proposed rule, we proposed continuing to defer to State law on the issue of authorized representatives of enrollees in the appeals process.

We did not believe that the Congress intended for the Secretary to regulate matters for which the Secretary was not authorized to promulgate standards (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues. However, because we do have the authority to regulate in the field of grievances, we were concerned that State grievance requirements would now be preempted, thereby requiring us to reexamine our Federal grievance requirements. We requested comments on this preemption issue and the specific State grievance requirements that should be incorporated into Federal regulatory requirements at § 423.564.

We also noted that tort law, and often contract law, are generally developed based on case law precedents established by courts, rather than by legislators through statutes or by State officials through regulations. In addition, we did not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between plans and their subcontractors. We believed that the Congress did not intend for our regulations to supersede each and every State requirement applying to plans—particularly those for which the Secretary lacks expertise and authority to regulate. Thus, we did not believe, for example, that wrongful death or similar lawsuits based upon tort law would be superseded by the appeals process established in these regulations. Similarly, State contract law would continue to govern private contract disputes between plans and their subcontractors.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee will still have State remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a stand alone PDP or an MA-PD plan.

Comment: We solicited comments on whether the proposed Federal grievance procedures should preempt State grievance requirements. We received several comments on this issue, which primarily supported adopting a single set of grievance procedures to reduce enrollee confusion and plan burden. Some commenters recommended that we adopt the provisions proposed by us for Medicare+Choice organizations in a January 24, 2001 proposed rule. See 66 FR 7,593. However, one commenter opposed Federal law preempting State law where Part D appeals are concerned.

Response: We agree with the commenters that establishing a uniform set of grievance standards will reduce confusion and burden for enrollees and plans. We also believe that one set of rules will ensure better beneficiary protections and achieve consistency among plan operations. Thus, § 423.564 implements the specific guidelines for Part D grievances that we proposed in January 2001 for Medicare+Choice organizations. We disagree with the commenter that Federal provisions should not preempt State requirements for appeals. We believe that such an approach is inconsistent with § 232(a) of the MMA, which preempts State appeal and grievance requirements and which is incorporated into the Part D laws through section 1860D–12(g) of the Act.

Under the grievance requirements, plans must notify enrollees of decisions as expeditiously as the enrollee's case requires, but no later than 30 calendar days after receiving a complaint. Plans may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or if the plan justifies a need for additional information and the delay is in the interest of the enrollee. We believe that the timeframes must be according to the enrollee's case as opposed to the enrollee's health since not all grievances involve medical care. For example, an enrollee may complain that a network pharmacy does not offer convenient hours for getting prescriptions filled. In addition, we believe that most plans will be able to respond to most grievances within 30 days. If an enrollee makes a grievance orally, the plan may respond to it orally or in writing, unless the enrollee requests a written response. If an enrollee files a written grievance, then the plan must respond in writing. In addition, a plan must provide information to enrollees on their right to request a review by a Quality Improvement Organization (QIO) if the grievance involves a quality of care issue. For any complaint involving a QIO, the plan must cooperate with the QIO in resolving the complaint. Plans must establish a 72-hour expedited grievance process for complaints involving certain procedural matters in the appeals process. Finally, plans must create a system to track and maintain records on all grievances.

We note that under MMA, enrollees will still have access to various State remedies available in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD plan.

9. Employer Sponsored Prescription Drug Programs and Appeals

As explained above, MA-PDs and PDPs are subject to the requirements of Part 423 for Part D benefits. In addition, when an employer, whether by contracting with an MA-PD, PDP, or otherwise, provides prescription drug benefits in addition to those covered under Part C and Part D of Title XVIII of the Act to their retirees, such employer may have established a group health plan governed by both Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and State law (to the extent such State law is not preempted by ERISA).

In drafting our Part C, MA rules, we consulted the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience under Part C, we have reason to believe that some Medicare eligible individuals may receive integrated prescription drug benefits, that is, Part D benefits through an MA-PD or PDP and supplemental benefits through an ERISA-covered plan. For example, an ERISA-covered plan could pay all or part of the retiree's cost sharing amount (for example, deductibles and coinsurance amounts specified in subpart C of Part 423) for a covered Part D drug provided through an MA-PD or PDP. Clearly, if the enrollee had a dispute about Part D coverage, he or she could file an appeal under the provisions in subpart M of Part 423. If the enrollee's dispute involved only the amount of cost sharing paid by the ERISA plan, he or she would file an appeal in accordance with the